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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/864,905	05/24/2001	Craig Harrison Miller	627-3271P	3099

7590

10/10/2002

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EXAMINER

LIU, HONG

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 10/10/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/864,905

Applicant(s)

Miller et al.

Examiner

Hong Liu

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above, claim(s) 11, 32, and 43-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-31, and 33-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 & 8 6) ☐ Other:

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1.

DETAILED ACTION

Claims 1-63 are pending in this application.

Election/Restriction

Applicant's election without traverse of Group III in Paper No. 7 is acknowledged. However, applicants failed to elect a species within the elected group as required by the written restriction. A telephone call was made to the undersigned attorney, David Bradin, and the Examiner was informed by the attorney that the applicants would like to elect the species: 3-(5-phenoxy-3-pyridyl)-3,7-diazabicyclo[3,3,1]nonane. The structure search was thus based on the core of the elected species, diazabicyclo[3,3,1]nonane. Applicants are expected to amend the definitions of u, v, w, x, and y such that the scope of the claims will be consistent with the core structure of the elected species. Claims 11, 32, and 43-63 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1-10, 12-31, and 33-42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The following reason(s) apply:

A limitation has been included in these claims that read “D” or “Z” is a non-hydrogen substituent. This limitation lacks description. Even negative limitations require a description. See MPEP at 2173.05(I). Applicant has failed to set the boundaries of the patent protection sought.

The nature of the invention in the instant application has claims which embrace a diversity of chemically and physically distinct compounds, wherein D and Z can be hydrogen or a non-hydrogen substituent group and Cy can be a any six-membered aromatic ring. Since no compounds with the diazabicyclo[3,3,1]nonane core are disclosed in the specification, there is insufficient guidance for preparing additional “nicotinic receptor antagonists” which would be effective since the cited examples are drawn to a homogenous group of compounds not remotely commensurate in scope to applicants’ claims. The specification also fails to disclose what starting materials, if there are any, are to be used to prepare the claimed compounds wherein Cx is aryl or heteroaryl. The specification on page 17 only discloses that an aryl halide could be coupled to 3,7-diazabicyclo[3.3.1]nonane to produce the desired the compounds. There is no suggestion of the sources of the aryl halide that is substituted with A-Cx. The starting material necessary to obtain the instant compounds must have been available as of the filing date in order to provide an enabling disclosure. See In re Howarth, 654 F.2d 103, 210 USPQ 689 (CCPA 1981); Ex parte

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Moersch, 104 USPQ 122 (POBA 1954). Since the chemical reactions to prepare the instantly claimed compounds would be extremely unpredictable given the random combinations of the substituents, applicants should show that the sources of these starting materials were common knowledge or readily available at the time of filing.

Furthermore, no testing data is provided for any of the compounds listed in the specification. Examples should be of sufficient scope as to justify the scope of the claim. The definitions of the various Z, Cy, D, and Cx variables on the ring system embrace many structurally divergent groups not represented at all in testing, since testing for the instant compounds is not seen in the specification. Markush claims must be provided with support in the disclosure when the “working examples” fail to include written description(s) which teach how to make and use Markush members embraced thereby in full, clear and exact terms. See *In re Fouch*, 169 USPQ 429.

This area of activity can be expected to be highly structure specific and unpredictable, as is generally true for chemically-based pharmacological activity. In view of the structural divergence in the claims, one skilled in the art could not reasonably extrapolate the activities of some of the claimed compounds to the other structurally divergent compounds embraced by the claims which have not been tested. In cases directed to chemical compounds which are being used for their physiological activity, the scope of the claims must have a reasonable correlation to the scope of enablement provided by the specification. See *In re Surrey* 151 USPQ 724 regarding sufficiency of

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disclosure for a Markush group. No reasonable assurance has been made that the instant compounds as an entire class have the required activities needed to practice the invention. Thus, factors such as “sufficient working examples”, “the level of skill in the art” and “predictability” have been demonstrated to be sufficiently lacking in the instant case for the scope being claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 6, 12, 22, and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- 1). Claims 1, 12, 22, and 33 are vague and indefinite in that the metes and bounds of the “non hydrogen substituent” is unknown.
- 2). The use of “heterocyclyl” in the definition of A, A', and Z is unclear to the array of heteroatoms, size of the rings, as well as nature of atoms as ring members. See *In re Wiggins* 179 USPQ 421 for certain terminology regarding heterocyclic ring systems.
- 3). “Substituted” heterocycle, cycloalkyl, or alkenyl throughout the claims is unclear as to the nature and number of substituent(s) intended. The metes and bounds are also unknown of the phrases “a substituent species” and “an aromatic group-containing species in claim 6.

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4). Claims 1, 12, 22, 33 are vague and infinite in that the scope of "having a sigma m value between about -0.3 and about 0.75" for substituents Z and D is unknown.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

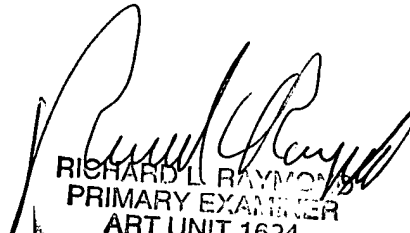
Claims 1-10, 12-31, and 33-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Czollner et al. (WO 97/40049). The reference teaches a generic group of compounds which embraces applicant's instantly claimed compounds. See formula III, page 8 wherein n can be 2, R22 is a substituted aryl or heteroaryl, etc. The compounds are taught to be useful as pharmaceutical agents for central nervous system disorders. The claims differ from the reference by reciting a specific species and/or a more limited genus than the reference. However, it would have nevertheless been obvious to one skilled in the art at the time of the invention to be motivated to select any of the species of the genus taught by the reference including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the specie of the genus would have similar properties and, thus, the same use as taught for the genus as a whole. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by

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the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus. See *In re Susi*, 440 F.2d 442, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in *Merck & Co. V. Biocraft Laboratories*, 847 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

Any inquiry concerning this communication should be directed to Examiner Hong Liu whose telephone number is (703) 306-5814. The examiner can normally be reached on Monday through Friday from 8:30 AM to 6:00 PM. If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached at (703) 308-4716. The fax phone number for this group is (703) 308-4734 for "unofficial" purposes and the actual number for **official** business is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose number is (703) 308-1235.

hl
October 6, 2002



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